Subcommittee on Criminal Justice, Drug Policy and Human Resources

Opening Statement of Chairman Mark Souder

"Sick Crime: Counterfeit Drugs in the United States"

November 1, 2005

Good afternoon, and thank you all for being here.

We are here because selling fake prescription drugs within the United States is a serious public threat, and it is a growing problem. This hearing will examine

- the vulnerabilities that allow counterfeit or substandard drugs to end up in legitimate pharmacies;
- how such vulnerabilities expose this nation to devastating terrorist attacks through our medicines;
- and the anticipated, widespread counterfeiting of a life-saving avian flu treatment in the midst of a potential pandemic, compounding the deadly toll of an outbreak. (Just this morning, the President asked Congress for 1.2 billion dollars for vaccines to prepare for an avian flu pandemic. We simply cannot risk vaccinating Americans with counterfeit therapies.)

This is a very serious issue to which we are calling our attention.

According to the World Health Organization, 10 percent of global pharmaceutical commerce this year will be counterfeit. That number is expected to double by the year 2010, as international criminal organizations become more sophisticated. Last year, within the United States, the FDA's counterfeit drug investigations rose 150% in only twelve months.

One key to understanding this disturbing problem is the so-called "gray market," which stems from the practice of drug diversion. Drug diversion is the principal method by which counterfeits consistently enter the legitimate drug market. The FDA confirmed with Subcommittee staff that drug diversion was the entry point for every case investigated by that agency involving counterfeit drugs going into legitimate pharmacies.

For example, "Closed door" or "own use" pharmacies are primary sources for diversion. "Own use" pharmacies, such as at nursing homes or hospitals, agree to provide medication solely to their own patients. Accordingly, such pharmacies acquire medication at a price much lower than wholesale. This opens the door to fraud, exemplified by some "own use" pharmacies overstating their patient populations, receiving surplus drugs, then selling them at a higher price into the gray market. Once drugs are on the gray market, they may be bought and sold dozens of times, passed among several hands, repackaged, mishandled, or relabeled.

This happens easily because the pharmaceutical supply chain is not regulated by any single entity, private or governmental. The pharmacies within a state are monitored by the state Boards of

Pharmacy, which enforces the standards of care within each state. However, the state Boards of Pharmacy lack police power, and many are limited to only a handful of inspectors. Drug manufacturers have to comply with the FDA for the safety, effectiveness, and labeling of their drugs. But drug manufacturers typically exercise no control over their drugs once they are shipped out of the manufacturing facility. Rather, the drugs are bought and sold by distributors, and frequently pass in and out of the secondary market.

Distributors, like retailers and physicians, are licensed by the states, which must only meet the minimal standards set by the Prescription Drug Marketing Act. *Please display the first illustration*. In order to obtain a distributor's license, some states' licensing requirements are more lenient than others. Lenient licensing standards provide an opportunity for unscrupulous distributors to legitimately buy and sell pharmaceuticals. One of the most notorious recent counterfeit drug busts, the Carlow case – which we'll hear more about in our second panel - involved a convicted felon who obtained a state distributor license in Florida.

As you can see on this map, eleven states, including Florida, have recently toughened their licensing standards for distributors. However, this leaves a patchwork of laws across the country, allowing for unscrupulous distributors to obtain legitimate state licenses and trade drugs on the secondary market. This situation of inconsistent standards throughout the country has prompted the Healthcare Distribution Management Association, or "HDMA," to recently advocate uniform federal licensing standards for prescription drug distributors. Having a private business association advocate rigorous federal licensing standards is something we rarely see. But it is clear that the gravity of this problem, and the issues at stake, have prompted the HDMA to take this radical step in order to promote the safety and security of our nation's drug supply.

Nevertheless, the current system allows drugs to pass through several middle-men before reaching a patient's hands. When unscrupulous middle-men resell the drugs, they sometimes re-label them to reflect higher (and more valuable) doses, mishandle them to contaminate or degrade the drug, or substitute fake products for the legitimate goods. *Please display the second illustration*. This is a photo of a legitimate tablet of Lipitor, a popular cholesterol-lowering drug, and a suspected counterfeit. They are virtually indistinguishable. The FDA recently indicted eleven individuals, a drug repacker and two wholesale distributors in cases related to the sale of Lipitor.

Please display the third illustration. This is a close-up photo of Lipitor's registered trademark. The measurement in the upper left hand corner shows the scale as one-twentieth of a millimeter, which is incredibly small. While a microscopic examination can reveal the counterfeiting, the naked eye may not.

With a vulnerable supply chain, counterfeit or substandard drugs like this counterfeit Lipitor can end up on the shelves of a trusted pharmacy, and ultimately distributed to unsuspecting victims.

For the patient, there is no commercial transaction like this. The patient has virtually zero ability to inspect the drugs' packaging, or compare it to other samples. The patient who goes to a pharmacy to have his or her prescription filled is helpless in determining the quality of the drug, and completely dependant on a system that has experienced some tragic breaches. Moreover, it is impossible to measure the scope of the problem, and we cannot say with any degree of certainty how many, or which, counterfeit drugs make it to the pharmacy shelves because a health indication, or ultimate death, may be attributed to a patient's underlying illness rather than the drug.

One way to verify a drug's authenticity is through a "pedigree" which would show the drug's chain of custody. Some of the states that have toughened their licensing standards for distributors, such as Florida, will soon require paper pedigrees for every drug purchased within that state. However, the FDA has delayed until December, 2006 the effective date for national regulations requiring a pedigree, in the hopes that an electronic track-and-trace program such as Radio Frequency Identification, or "RFID," will be viable.

The FDA has reported to Subcommittee staff that their Office of Criminal Investigations, or "OCI," has turned out 71 indictments on their counterfeit drug cases, many of which involved multiple counts, leading to 67 convictions so far. Several more cases, not yet in the formal judicial process, are in the pipeline. Moreover, OCI's robust investigations have interdicted counterfeit drugs that would have otherwise made it to pharmacy shelves. However, significant vulnerabilities in the system still exist.

In addition to providing a way for unscrupulous enterprises to obtain massive profits by distributing phony, high-priced drugs, the vulnerabilities in the system provide a way for terrorists to target our citizens. One frightening and widely discussed scenario, among dozens of possibilities of how terrorists might exploit our vulnerabilities in this area, involves a deliberate anthrax "scare" in order to trigger a run on Cipro, the antibiotic used for fighting the anthrax poison. A phony, and deadly version of this medicine, having already been injected without detection into the nation's pharmaceutical stream by terrorists, would then cause thousands more deaths. Baz Mohammad, a Taliban-linked narco-terrorist who was recently extradited from Afghanistan, defends a "Jihad" of taking Americans' money at the same time the drugs we are paying for kill us.

Finally, the counterfeit drugs issue is well illustrated by the immediate, worldwide concern over an Avian Flu outbreak and the FDA's announcement last week that it anticipates an increase in the sale of counterfeit or fraudulent treatments for such a pandemic. Tamiflu, currently the only known treatment for this virus strain, is expected to be widely counterfeited. Counterfeit treatment in the midst of such a pandemic would most certainly compound the deadly toll of the flu.

I do not want to wait until there are catastrophic "failures" in the system to examine the problems that allow counterfeit drugs into our pharmaceutical market. The time for examining and acting on this problem is now.

Our first panel today is Mr. Randall Lutter, Acting Associate Commissioner for Policy and Planning at the Food and Drug Administration.

The second panel consists of Katherine Eban, author of Dangerous Doses; and family members of two patients who were victims of counterfeit drugs purchased at mainstream pharmacies: Kevin Fagan, the father of Timothy Fagan, who received counterfeit Epogen after his liver transplant operation; and Max Butler, the brother of Maxine Blount, who received counterfeit Procrit in the midst of her battle against breast cancer.

The third panel consists of Peter Pitts, from the Center for Medicines in the Public Interest; Carmen Catizone, Executive Director of the National Association of Boards of Pharmacy; Jim Dahl, Former Assistant Director of Investigations, FDA Office of Criminal Investigations; and Donald deKeiffer, of deKeiffer and Horgan.